



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Zemcelpro

### Procedural steps taken and scientific information after the authorisation\*

\*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
Variation type IB /	C.I HUMAN AND VETERINARY MEDICINAL	22/12/2025		SmPC,	To update the SmPC by correcting the Leukopenia

<sup>1</sup> Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



EMA/VR/0000316958	<p>PRODUCTS - C.I.z Other variation - Accepted</p> <p>C.I.z (Type IB) – To update the SmPC by correcting the Leukopenia percentage in Section 4.8 and the data for Acute Lymphoid Leukaemia and Myelodysplastic Syndrome in Section 5.1. In addition, the MAH took the opportunity to implement editorial changes to (1) update the MAHs phone number in the Annexes, (2) correct a translation error in the FR SmPC, and (3) correct a typographical error in the FI SmPC.</p>			Labelling and PL	percentage in Section 4.8 and the data for Acute Lymphoid Leukaemia and Myelodysplastic Syndrome in Section 5.1.
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